

In the Claims

Amend claim 1 as follows:

Claim 1.(Amended) A one-piece sterile [disposable] non-invasive dispenser for the rapid irrigation and debriding of wounds and incisions, which is disposable in any container, comprising:

a flexible chamber having an internal volume containing a sterile solution, said chamber having an orifice at one end thereof;

a non-invasive nozzle having a first opening at one end and a second opening at the other end thereof, wherein said first opening is affixed to said orifice of said chamber; and said second opening dispenses said solution;

a protective tip affixed to said second opening of said nozzle, thereby maintaining said solution in a sterile state; and

a removable packaging band around said protective tip.

RESPONSE

Applicants seek to amend, for clarity, the specification to include the word “non-invasive” as shown. The justification for this amendment is that all wound irrigation and debriding systems are inherently non-invasive, unlike, for example, enemas which penetrate the body.

Applicants also seek to amend claim 1 to include the phrase “non-invasive” as well as the following terms and phrases already shown in the specification: “one-piece” (page 1, line 35); “rapid” (page 1, line 36, page 2, line 1); “which is disposable in any container” (page 2, lines 6-7, page 3, lines 37-40).

Examiner has rejected claims, 1,3,4 and 5 under 35 U.S.C. 102 (b) as anticipated by Hussey. Applicants respectfully traverse this rejection for the following reasons:

Hussey describes an enema unit comprising bottle 10, rectal tip 15 with a break-off tab 20 which, in turn consists of a spherical ball 20 mounted on top of the tip so as to completely enclose the circular passage through the tip, in an attempt to prevent any contamination or spillage of the fluid. The ball is removed by twisting it. The tip is coated with a lubricant. A sleeve 30 is slid over the tip and heat-shrunk so as to protect the lubricant on the tip from contamination (col.3, lines 1-26). The lubricant is needed precisely because of the nature of an enema. It is inherently intrusive.

Applicants' invention is a wound irrigation unit. It does not require lubricating the nozzle and is not intrusive. Although not considered necessary, Applicants seek to amend their specification and claims to more clearly reflect this fact. Wound irrigation debriding, as opposed to an enema inherently connotes non-invasiveness. Applicants solve the problems of preventing contamination, tampering, and spillage by a single-unit dispenser, which includes a protective tip at the end of the nozzle around which is wrapped a protective band. Applicants' invention thus addresses the needs of a wound irrigation system that is contaminant-free, cannot be tampered with prior to use, is ready for instant use under emergency conditions, and can be discarded without concern for complying with Sharps Hazards regulations. Applicants respectfully suggest that the lubricant coated tip and the closure system patented by Hussey, requiring a break-off tab, a twist-off ball, and a heat-shrunk sleeve is so substantially different from Applicants wound irrigation system as not to anticipate under §102 (b).

Hussey's system requires a more complicated tip and protective sleeve for the lubricant presently because it is an invasive enema, not a wound irrigation system. Hussey's enema unit is in a different art field than Applicants' wound irrigation system. Applicants' invention is concerned not just with sterility of solution, but with rapid delivery and simple disposability without the requirements of Sharps Hazards regulations.

As to claims 3, 4, and 5, Applicants have previously, in a response dated 01/15/00, stated that these claims do not constitute patentably distinct species. Applicants

have never claimed these as separately patentable species. However, these variations cannot be evaluated alone but as a further limitation of claim 1 on which they rely and with which they merge as dependent claims.

Claim 2 has been rejected under 35 U.S.C. 103 (a) as unpatentable over Hussey in view of Reddick. This rejection is respectfully traversed for the reasons noted below.

If, as Applicants contend, Hussey does not anticipate Applicant's invention since Hussey does not contain each and every limitation of Applicants' invention, then it should be immaterial whether Reddick's filters would have been obvious to modify Hussey.

Applicants do not claim the use of a filter in their invention as novel per se. Rather, dependent claim 2 incorporates all of the elements of independent claim 1, adding the filter as a further limitation. Within this context, Applicants contend that selectively choosing the filters of Reddick's douche apparatus to add to Hussey's enema unit does not constitute the obviousness of Applicant's invention.

Likewise, claim 6 is rejected under 35 U.S.C. 103 (a) as unpatentable over Hussey in view of Rose. Rose describes and claims a nasal douche which is inserted "snugly into the nostril". (Line 40.) Here, again, Applicants have never claimed that the angle of their nozzle is per se patentable. Applicants repeat and reaffirm all of the same arguments against a finding of obviousness over their invention as they did for the previous reference of Reddick in view of Hussey, except that the argument here refers to angled nozzles rather than filters.

Examiner rejects claims 7 and 8 under 35 U.S.C. 103 (a) as unpatentable over Hussey in view of Wallace et al. Applicants agree with Examiner that Hussey does not disclose a dispenser having a sterile solution containing sodium chloride and/or distilled water. Hussey describes and claims an enema. Wallace et al describes and claims

polymeric compositions and methods. One means of delivering the hydrogel of the Wallace invention is a syringe. (See, for example, Figs. 1, 2A, 3A.)

Applicants respectfully disagree with Examiner's position that claims 7 and 8 are rendered obvious in view of these two references. Applicants also respectfully disagree that the enema dispenser of Hussey would be an obvious alternative to Applicants' dispenser, considering the totality of Applicants' wound dispenser and debriding system.

Nevertheless, Applicants are not claiming the sterile solutions of claims 7 and 8 as patentable per se. They do assert, however, that the entire invention as claimed, taken in its entirety is patentable, when the dependent claims are read in conjunction with the independent claim.

Applicant's invention addresses the needs of the medical art dealing with wound irrigation and debriding, particularly under emergency conditions, where time is of the essence, sterility of the unit is essential, and disposability and economy is important.

For all of the reasons explained above and in the previously filed substantive response, Applicants respectfully suggest this case is in condition for allowance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Arthur A. Smith, Jr.", with a stylized flourish at the end.

Arthur A. Smith, Jr.

Reg. No. 24,178

Dated: November 14, 2001



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Arthur A. Smith, Jr.

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